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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,214	Applicant(s) TANAKA, HAYAO
	Examiner Walter B Aughenbaugh	Art Unit 1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____ .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7 is/are rejected.

7) Claim(s) 8-11 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION

Claim Objections

1. Claims 8-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8-11 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed saturation adsorption amounts of claims 1 and 7 seem to be arbitrary. The identities of the molecules used (including size), the temperature, concentration of the solution and the pH of the solvent that enable use of the invention are not disclosed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, the claim should positively set forth the purpose of the container and the structure necessary for carrying out the purpose, i.e., the claim is incomplete in regard to the

to the structure of the container. No structure is claimed for the container; therefore, the scope of the claim cannot be ascertained.

In further regard to claim 1, the phrase "the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less" is indefinite due to the fact that the saturation adsorption amount is dependent on the molecule used for the assay, among other conditions such as the solution used for the assay and the concentration of the particular molecule in the solution used for the assay. The saturation adsorption amount of a molecule in a solution would be attained according to the desired end result of the user via selection of a particular molecule, solution and concentration, etc.; therefore, the limitation "the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less" is not given patentable weight. Furthermore, the portion of the container that this saturation adsorption amount is being claimed for is unclear- is this an average over the entire inside portion of the container, or is this amount intended for only a portion of the inside of the container? If the amount is intended for only a portion of the container, the structure of this portion, including the physical bounds of the portion, must be associated with this amount in the claim.

In regard to claims 2 and 3, the relative term "highly" is indefinite (the term "highly" appears twice in third line of claim 2 and in line 3 of claim 3). The claims are incomplete in regard to the structure of the container with respect to the "inner surface". What does "an inner surface" constitute? The entire "inner surface" of the container? Only a portion of the container?

In regard to claims 4-6, the phrase "the contact angle between the inner surface of the container and water" renders the claims indefinite. It is unclear whether "the contact angle" is

intended to be a structural limitation of the container or is a measurement of the hydrophilicity of the polymer of claim 3. The relationship between each of claims 4-6 and claim 3 must be more particularly pointed out. Furthermore, the claimed contact angles, taken as a measurement of the hydrophilicity of the polymer of claim 3, are dependent on the polymer chosen as the hydrophilic polymer of claim 3. However, no polymer is specified in the claims that claims 4-6 depend on; consequently, the scope of the claims cannot be ascertained.

In regard to claim 7, the phrase "the saturation adsorption amount of molecules used for the assay is 1×10^{-3} pmol/cm² or less" is indefinite for the same reasons that render the phrase "the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less" of claim 1 indefinite as discussed above.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox.

Fox teaches a reaction well with a bottom wall that has an inner surface that is hydrophilic and side walls that have hydrophobic inner walls (col. 2, lines 15-29). Fox teaches that the bottom of the well is coated with a hydrophilic material or the inner surface 32 of the bottom wall 28 is made from a hydrophilic plastic (col. 2, lines 25-30 and Figure 4). Fox teaches that an aqueous solution spread relatively evenly across the bottom of the wells in all samples tested (col. 8, lines 20-23), therefore, the contact angle of the aqueous solution on the bottom of

the well approaches a contact angle of zero, a condition which reads on the contact angle values “30° or less”, “15° or less” and “1° or less” of claims 4-6. Furthermore, the claimed contact angles, taken as a measurement of the hydrophilicity of the polymer of claim 3, would be attained according to the desired end result of the user via selection of a particular polymer used to construct or coat the inner surface of the bottom of the well. Note that the limitation “the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less” is not given patentable weight since the saturation adsorption amount of a molecule in a solution would be attained according to the desired end result of the user via selection of a particular molecule, solution and concentration, etc.

8. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al.

Levy et al. teach a hydrophobic cuvette, the inner surface of which is coated with a hydrophilic polymer (col. 4, lines 41-45). Note that Levy et al. teaches the use of poly(hydroxyethyl methacrylate as the hydrophilic polymer) (col. 4, lines 52-59), a condition which reads on claim 9, which is not being treated on its merits in this action. Furthermore, the claimed contact angles, taken as a measurement of the hydrophilicity of the polymer of claim 3, would be attained according to the desired end result of the user via selection of a particular polymer used to coat the inner surface of the cuvette. Note that the limitation “the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less” is not given patentable weight since the saturation adsorption amount of a molecule in a solution would be attained according to the desired end result of the user via selection of a particular molecule, solution and concentration, etc.

9. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler.

Buechler teaches a diagnostic device with time gate 5 leading into reaction chamber 4 (col. 7, lines 41-42 and Figure 1B). The time gate is a capillary channel with hydrophobic surfaces (col. 7, lines 58-67) and serves as a barrier to a hydrophilic liquid (col. 7, lines 53-58). The hydrophobic barrier is changed to a hydrophilic zone when a certain component of the reaction mixture binds to the hydrophobic capillary channel walls (col. 8, lines 7-10). Buechler teaches that this component is chosen from various proteins, polypeptides or polymers (note that proteins and polypeptides are polymers) (col. 8, lines 17-23). The hydrophobic surface of the capillary channel is therefore essentially coated with a hydrophilic polymer to enable the hydrophilic reaction mixture to flow through the capillary. Furthermore, the claimed contact angles, taken as a measurement of the hydrophilicity of the polymer of claim 3, would be attained according to the desired end result of the user via selection of a particular polymer used as the surfaces of the capillary. Note that the limitation "the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less" is not given patentable weight since the saturation adsorption amount of a molecule in a solution would be attained according to the desired end result of the user via selection of a particular molecule, solution and concentration, etc.

10. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Oberhardt.

Oberhardt teaches a reaction slide 1 with reaction volume 66 (col. 13, lines 3-7 and Figure 31). Oberhardt teaches the treatment of the internal surfaces of the reaction slide to increase the hydrophilic character of the internal surfaces of the reaction slide and to therefore decrease the contact angle (col. 14, lines 21-27). Oberhardt teaches the use of polyoxyethylene derivative type and polyoxyethylene ether type surfactants as polymeric wetting agents to

decrease the contact angle of the internal surfaces of the reaction slide (col. 14, lines 28-41).

Oberhardt teaches that the surface properties of the materials should be such that appropriate wetting of the surface, which is indicated by a low contact angle, is achieved to provide proper flow conditions (col. 14, lines 58-63). Furthermore, the claimed contact angles, taken as a measurement of the hydrophilicity of the polymer of claim 3, would be attained according to the desired end result of the user via selection of a particular polymeric wetting agent used to treat the internal surfaces of the reaction slide. Note that the limitation "the saturation adsorption amount of molecules used for the assay is 1×10^{-1} pmol/cm² or less" is not given patentable weight since the saturation adsorption amount of a molecule in a solution would be attained according to the desired end result of the user via selection of a particular molecule, solution and concentration, etc.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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12. Claims 1 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Fox in view of applicants' admission. Fox teaches the reaction well as discussed above. Fox fails to teach a saturation adsorption amount. Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm² or more (pages 6-7 of applicants' specification). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have identified a combination of a particular polymer used to construct or coat the inner surface of the bottom of the well and a particular molecule (and to have identified a particular concentration range of the particular molecule in solution) in order to achieve the claimed saturation adsorption amounts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

13. Claims 1 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. in view of applicants' admission. Levy et al. teach the cuvette as discussed above. Levy et al. fails to teach a saturation adsorption amount. Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm² or more (pages 6-7 of applicants' specification). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have identified a combination of a particular polymer used to coat the inner surface of the cuvette and a particular molecule (and to have identified a particular concentration range of the particular molecule in solution) in order to achieve the claimed saturation adsorption amounts, since it has been held that discovering an

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optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

14. Claims 1 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler in view of applicants' admission. Buechler teaches the capillary channel as discussed above. Buechler fails to teach a saturation adsorption amount. Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm² or more (pages 6-7 of applicants' specification). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have identified a combination of a particular polymer used to coat the inner surface of the capillary channel and a particular molecule (and to have identified a particular concentration range of the particular molecule in solution) in order to achieve the claimed saturation adsorption amounts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

15. Claims 1 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt in view of applicants' admission. Oberhardt teaches the reaction slide as discussed above. Oberhardt fails to teach a saturation adsorption amount. Applicants disclose that in a conventional polystyrene or polypropylene container for an immunoassay, the adsorption amount of molecules is about 1-10 pmol-cm² or more (pages 6-7 of applicants' specification). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have identified a combination of a particular polymer used to treat the internal surfaces of the reaction slide and a particular molecule (and to have identified a particular concentration range of the

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particular molecule in solution) in order to achieve the claimed saturation adsorption amounts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. 5,211,913 to Hagiwara et al., U.S. 5,554,536 to Rising and G.B. 1,401,233 to Wichterle.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B Augenbaugh whose telephone number is 703-305-4511. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 703-308-4251. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

wba
08/09/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

8/9/02